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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,503	02/18/2004	Matthew F. Ogle	3126.03US02	2970

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EXAMINER	
MEHTA, BHISMA	

ART UNIT	PAPER NUMBER
3767	

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12/31/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,503	OGLE ET AL.	
	Examiner	Art Unit	
	BHISMA MEHTA	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-35,37 and 47-55* is/are pending in the application.

4a) Of the above claim(s) *48 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-35,37,47,49,50 and 52-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 4, 2009 has been entered.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose each of the surface capillary fibers comprising a capillary along its outer surface running along at least a portion of the length of the surface capillary fiber. There is support for the surface capillary fiber having a capillary along its outer surface as shown in Figure 1 and as discussed by Applicant in lines 1-4 of page 9 of the Remarks filed November 4, 2009. There is also support for the capillary running along at least a portion of the length of the surface capillary fiber in lines 26-30 of page 11 of the specification. However, the specification does not disclose the specifics of the surface capillary fiber having a capillary along its outer surface. Therefore, it is suggested that the specification be amended to include the language of each of the surface capillary fibers comprising a

capillary along its outer surface running along at least a portion of the length of the surface capillary fiber.

Claim Objections

3. Claims 20-35, 37, 47, 49, 50, and 52-55 are objected to because of the following informalities: There is a grammatical error in the use of "each of the surface capillary fiber" in line 6 of claim 20, in line 5 of claim 28, in line 4 of claim 34, and in line 4 of claim 47. It is suggested that "each of the surface capillary fiber" be replaced with" each of the surface capillary fibers" in the appropriate lines of claims 20, 28, 34, and 47. Claim 50 recites the limitation "the interior lumen" in line 2. There is insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20-27, 53, and 54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The use of "the surface capillary fiber" in line 3 of claim 20 is unclear as to whether a quantity of bioactive agent is associated with one of the surface capillary fibers or if a quantity of bioactive agent is claimed as being associated with each of the surface capillary fibers. The use of "the fiber" and "the surface capillary fiber" in lines 4-5 of claim 20 is also unclear as to whether the

specifics of the elution of the bioactive agent is being claimed with respect to one of the surface capillary fibers or all of the plurality of surface capillary fibers. This also applies to the use of "the surface capillary fiber" in line 2 of claim 25 as it is unclear which one of the plurality of surface capillary fibers is being claimed as having a surface area of at least about a factor of 1.5 greater than a corresponding circular fiber with an equivalent diameter.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 20, 21, 24, 26-31, 33-35, 37, 47, 49, 50, 54, and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Olsen et al (U.S. Patent No. 7,326,196).

Olsen et al disclose a medical device or catheter (12) comprising a plurality of surface capillary fibers or filaments (36, 38) associated with at least a portion of a surface of the device (as disclosed in lines 43-65 of column 3, the fibers or filaments are associated with the exterior surface and the lumen (24) of the catheter (12)). See Figure 1. In lines 4-9 of column 4, Olsen et al disclose the filaments as being a polymeric line or a fiber. Also, the filaments (36, 38) are considered to be a plurality of

fibers as the filaments are elongated thread-like structures and, therefore, are fibers (Figures 1-8 and line 43 of column 3 to line 12 of column 4). Furthermore, in lines 4-12 of column 4, Olsen et al disclose that the filaments or fibers have a cross sectional shape such as splined or star shape and, thus, each of the filaments or surface capillary fibers has a capillary along its outer surface running along at least a portion of the length of the surface capillary fiber. Also, as disclosed in lines 31-66 of column 4, the surface capillary fibers or filaments (36, 38) form fluid pathways along an exterior surface of the fibers. The fibers comprise a polymer (lines 4-9 of column 4). In line 60 of column 4 to line 5 of column 5, Olsen et al disclose that a quantity of bioactive agent is associated with the surface capillary fibers, specifically portions (52, 54) of the surface capillary fibers (36, 38), such that the bioactive agent can elute in a controlled way from the fiber or fibers when the surface capillary fiber (or fibers) is contacting a patient's body fluids or tissue. In lines 60-64 of column 4, Olsen et al disclose that the medical device is a percutaneous device or an implantable device. As to claims 21 and 24, Olsen et al disclose the bioactive agent as an anti-microbial agent as the antibiotic disclosed in lines 2-5 of column 5 is an anti-microbial agent (a substance capable of destroying or inhibiting the growth of microorganisms). As to claim 26, the device (12) is configured for placement within a blood vessel without blocking flow through the vessel as the device is capable of being placed within a blood vessel without blocking flow through the vessel. As to claim 27, the device comprises a catheter (12) and additional surface capillary fibers where the additional surface capillary fibers are associated with the inner surface of the catheter as Olsen et al disclose that the device

may have three or more surface capillary fibers or filaments extending from a port of the catheter or outwardly extending from the catheter, and, therefore being associated with the inner surface of the catheter. As to claim 54, the plurality of surface capillary fibers or filaments (36, 38) are associated with at least a portion of a surface of the device with an adhesive, mechanical binding, heat bonding, or chemical bonding as indicated in lines 13-30 of column 4 where the plurality of surface capillary fibers are associated with the exterior surface (18) by mechanical binding of the retainer (44) around the catheter (12) or attachment of the retainer over portions of the filaments by adhesive.

As to claim 28, Olsen et al disclose a tubular medical device (12) having a tubular substrate with an interior surface (16) and an exterior surface (18) where a plurality of surface capillary fibers or filaments (36, 38) are associated with at least a portion of one of the surfaces with an adhesive, mechanical binding, heat bonding, or chemical bonding as indicated in lines 13-30 of column 4 where the plurality of surface capillary fibers are associated with the exterior surface (18) by mechanical binding of the retainer (44) around the catheter (12) or attachment of the retainer over portions of the filaments by adhesive. The filaments (36, 38) are considered to be a plurality of fibers as the filaments are elongated thread-like structures and, therefore, are fibers (Figures 1-8 and line 43 of column 3 to line 12 of column 4). Furthermore, in lines 4-12 of column 4, Olsen et al disclose that the filaments or fibers have a cross sectional shape such as splined or star shape and, thus, each of the filaments or surface capillary fibers has a capillary along its outer surface running along at least a portion of the length of the surface capillary fiber. Also, as disclosed in lines 31-66 of column 4, the

surface capillary fibers or filaments (36, 38) form fluid pathways along an exterior surface of the fibers. As to claims 29 and 30, the device (12) is a catheter (12) configured for placement within a vessel of a patient as the catheter is capable of being placed within a vessel of a patient and the catheter (12) is a microcatheter as it is capable of being placed within the narrow vessels of a patient. As to claim 31, the surface capillary fibers or filaments (36, 38) are associated with a bioactive agent (line 60 of column 4 to line 5 of column 5). As to claim 33, at least one of the surface capillary fibers is associated with at least a portion of the interior surface (16) as the fibers or filaments (36, 38) extend into the lumen (24) which is formed by or is a part of the interior surface (16).

As to claim 34, Olsen et al disclose a medical device (12) comprising a non-porous surface (18), at least a portion of which is covered with surface capillary fibers or filaments (36, 38). The surface is contoured to match a portion of a structure within a patient as the tubular sidewall (14) would match a blood vessel within a patient. In lines 4-9 of column 4, Olsen et al disclose the filaments as being a fiber. Also, the filaments (36, 38) are considered to be a plurality of fibers as the filaments are elongated thread-like structures and, therefore, are fibers (Figures 1-8 and line 43 of column 3 to line 12 of column 4). Furthermore, in lines 4-12 of column 4, Olsen et al disclose that the filaments or fibers have a cross sectional shape such as splined or star shape and, thus, each of the filaments or surface capillary fibers has a capillary along its outer surface running along at least a portion of the length of the surface capillary fiber. Also, as disclosed in lines 31-66 of column 4, the surface capillary fibers or filaments (36, 38)

form fluid pathways along an exterior surface of the fibers. In lines 60-64 of column 4, Olsen et al disclose that the medical device is a percutaneous device or an implantable device. As to claim 35, in lines 65-67 of column 2, Olsen et al disclose the non-porous surface comprising a polymer. As to claim 37, the surface capillary fibers or filaments (36, 38) are associated with a bioactive agent (line 60 of column 4 to line 5 of column 5).

As to claim 47, DiCarlo et al disclose a method for delivering a bioactive agent using a medical device (12) where a patient's body fluids/tissues contact a plurality of surface capillary fibers or filaments (36, 38) associated with at least a portion of a surface of the device (lines 31-59 of column 4). The fibers or filaments are associated with the exterior surface and the lumen (24) of the device (12). See Figure 1. In lines 4-9 of column 4, Olsen et al disclose the filaments as being a fiber. Also, the filaments (36, 38) are considered to be a plurality of fibers as the filaments are elongated thread-like structures and, therefore, are fibers (Figures 1-8 and line 43 of column 3 to line 12 of column 4). Furthermore, in lines 4-12 of column 4, Olsen et al disclose that the filaments or fibers have a cross sectional shape such as splined or star shape and, thus, each of the filaments or surface capillary fibers has a capillary along its outer surface running along at least a portion of the length of the surface capillary fiber. Also, as disclosed in lines 31-66 of column 4, the surface capillary fibers or filaments (36, 38) form fluid pathways along an exterior surface of the fibers. In line 60 of column 4 to line 5 of column 5, Olsen et al disclose that the capillaries of the fibers, specifically portions (52, 54) of the surface capillary fibers (36, 38), are associated with a bioactive agent such that the bioactive agent elutes in a controlled way from the fibers. In lines 60-64 of

column 4, Olsen et al disclose that the medical device is a percutaneous device or an implantable device. As to claim 49, contacting of the patient's fluids or tissue comprises delivery of a catheter (12) associated with the surface capillary fibers as disclosed in lines 31-50 of column 4. As to claim 50, the surface capillary fibers or filaments (36, 38) are associated with the interior lumen (24) of the catheter (12) (lines 43 of column 3 to line 1 of column 4). As to claim 55, the plurality of surface capillary fibers or filaments (36, 38) are associated with at least a portion of a surface of the device with an adhesive, mechanical binding, heat bonding, or chemical bonding as indicated in lines 13-30 of column 4 where the plurality of surface capillary fibers are associated with the exterior surface (18) by mechanical binding of the retainer (44) around the catheter (12) or attachment of the retainer over portions of the filaments by adhesive.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 22, 32, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of DiCarlo et al (U.S. Patent No. 6,929,626). Olsen et al disclose the device and method substantially as claimed. Even though Olsen et al disclose a bioactive agent, such as an anti-microbial agent, associated with the surface capillary fibers, Olsen et al are silent on the specifics of the bioactive agent

comprising a thrombolytic agent such as heparin sulfate. In lines 35-50 of column 5, DiCarlo et al disclose a device having a textile material made up of fibers where a bioactive agent such as a thrombolytic agent or an anti-microbial agent is associated with the fibers in the same field of delivering a bioactive agent to a site in a patient's body. The thrombolytic agent may include heparin sulfate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide as the bioactive agent disclosed by Olsen et al a thrombolytic agent such as heparin sulfate as taught by DiCarlo et al as both Olsen et al and DiCarlo et al disclose a device with a bioactive agent, such as an anti-microbial agent, associated with the fibers of the device where the bioactive agent is to be delivered to a site in a patient's body and DiCarlo et al teach that it is well known to deliver a thrombolytic agent, such as heparin sulfate, to a treatment site by associating the thrombolytic agent with the fibers of the device.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of Samson et al (U.S. Patent No. 6,066,149). Olsen et al disclose the device substantially as claimed. Even though Olsen et al disclose a bioactive agent associated with the surface capillary fibers, Olsen et al are silent as to the specifics of the bioactive agent comprising tissue plasminogen activator (tPA). Samson et al disclose using a medical device or catheter to deliver bioactive agents such as tPA or urokinase (lines 19-27 of column 5) which are thrombolytic agents in the same field of delivering a bioactive agent to a site in a patient's body. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide as the bioactive

agent of Olsen et al a thrombolytic agent such as tPA as taught by Samson et al as both Olsen et al and Samson et al disclose medical device for delivering a bioactive agent and Samson et al teach that it is well known to use a thrombolytic agent such as tPA for the bioactive agent which is being delivered into the patient's body.

11. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. Olsen et al disclose the device substantially as claimed. Even though Olsen et al disclose the surface capillary fibers or filaments (36, 38) having a cross sectional shape such as a splined or star shape (lines 4-12 of column 4) and having a fluid pathway along the exterior surface of the fibers (lines 31-59 of column 4), Olsen et al are silent on the specifics of the surface capillary fiber having a surface area of at least about a factor of 1.5 greater than a corresponding circular fiber with an equivalent diameter. However, in lines 4-17 of column 2, Olsen et al disclose the need to induce an even movement of fluid across a target area. It would have been obvious to one having ordinary skill in the art at the time the invention was made that the splined or star shaped cross section of the fibers of Olsen et al would result in a surface area of at least about a factor of 1.5 greater than a corresponding circular fiber with an equivalent diameter as the splined or star shaped cross section would increase the surface area of the fiber as compared to a corresponding circular fiber. Additionally, it would also have been obvious to one having ordinary skill in the art at the time the invention was made to form the splined or star shaped cross section of the fiber such the surface area of the fiber would be at least about a factor of 1.5 greater than a corresponding circular fiber

with an equivalent diameter as this would allow for even movement of fluid across a target area.

12. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al in view of Bucay-Couto et al (U.S. Patent Application Publication No. 2003/0018306). Olsen et al disclose the device substantially as claimed. Even though Olsen et al disclose a bioactive agent associated with the surface capillary fiber where the fibers releasably contains the bioactive agent, Olsen et al are silent as to the specifics of the bioactive agent being associated with a controlled release agent. Bucay-Couto et al disclose using a medical device or catheter to deliver bioactive agents and teach associating the bioactive agent with a controlled release agent in order to control the release of the bioactive agent (paragraph [0035]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to associate the bioactive agent of Olsen et al with a controlled release agent as taught by Bucay-Couto et al as both Olsen et al and Bucay-Couto et al disclose medical device for delivering a bioactive agent and Bucay-Couto et al teach that it is well known to use a controlled release agent with the bioactive agent in order to extend the release time of the bioactive agent.

Response to Arguments

13. Applicant's arguments with respect to claims 20-35, 37, 47, 49, 50, and 52-55 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767